REMARKS

Claims 31-66 are pending in the application.

Claims 1-30 have been previously cancelled. Claims 32-34, 36, 38 and 39 are cancelled in this Amendment.

Claim 31 has been amended. Support for the amendment to claim 31 can be found in the Specification at page 19, lines 16-29 and in previous claim 34.

Claim 40 has been amended. Support for the amendment to claim 40 is found in the Specification at page 16, lines 29-32.

Claims 45 and 58 have been amended to italicize the genus of bacteria.

Claim 49 and 55 have been amended. Support for the amendments is found in the Specification page 16, last paragraph to page 17, first paragraph, and on page 6, first paragraph.

Claim 61 has been amended. Support for the amendment to claim 61 is found in the Specification at page 8, line 30 to page 9, line 12.

Claim 63 has been amended to be consistent with claim 61.

Claim 64 has been amended. Support for the amendment is found in the Specification at page 15, lines 5-18.

No new matter has been added.

Objections to the Specification

The Examiner objects to the Specification for informalities due to the recitation of an unneeded parentheses on page 1, the recitation of "found that a by 40%" on page 2 and the failure to italicize all bacterial names.

Applicants have amended the Specification by deleting the unneeded parentheses, clarifying the language on page 2 and italicizing the bacterial genus and species names. The language change on page 2 is supported by the disclosure of the Specification at page 37, lines 2-7. The italicization is customary in the art. Accordingly, no new matter has been added.

Applicants request that the objection be withdrawn.

Amendments to the Drawings

The Examiner objects to the Drawings filed on August 26, 2006 because the labeling of the number of the drawings is handwritten.

Applicants provide substitute drawings in this response. The substitute drawings have typewritten numbers, thus, no new matter has been added.

Applicants request that the objection be withdrawn.

Objections to the Claims

The Examiner objects to claims 33, 45, 52 and 58 because the bacterial names are not in italics.

Applicants have amended the claims thereby obviating the objection. Applicants request that the objection be withdrawn.

Rejections Under 35 U.S.C. § 112, second paragraph

Claim 62

The Examiner rejects claim 62 under 35 U.S.C. § 112, second paragraph as indefinite because the Examiner states "the claim is drawn to the 'use' according to claim 62." Applicants

assume that the Office Action contained a typographical error and that the Examiner intended to recite "claim 63" which contains the term "use."

Applicants have amended claim 63 by replacing "use" with "method," which is consistent with claim 62, from which claim 63 depends. Applicants request that the rejection be withdrawn.

Claims 31-39

The Examiner rejects claims 31-39 for recitation of the phrase "comprising administering to a patient in which thereof a therapeutically effective amount."

Applicants have corrected the typographical error so that the phrase now reads "comprising administering to a patient in need thereof a therapeutically effective amount." Therefore, Applicants request that the rejection be withdrawn.

Claims 40-48

The Examiner rejects claims 40-48 under 35 U.S.C. § 112, second paragraph as being incomplete for omitting essential steps, that is, the method of identification.

Claim 40 now recites "identifying the complex comprising the agent possessing at least one accessible sulphate and/or phosphate group and the polypeptide/nucleic acid as defined in" the previous step. Accordingly, Applicants submit that the claim is clear and request that the rejection be withdrawn.

Claims 49-54 and Claims 55-60

The Examiner rejects claims 40-48 and 55-60 under 35 U.S.C. § 112, second paragraph as being indefinite because it is unclear how one determines if one actually has "a shortened polypeptide or a shortened nucleic acid as compared to the full-length polypeptide or nucleic acid, and thus, how one determines if the result is actually indicative of an increase [sic] susceptibility."

Claims 40 and 55 now recite a shortened polypeptide or a shortened nucleic acid as compared to the full-length polypeptide or nucleic acid *as defined by SEQ ID NO: 1 or SEQ ID*

NO: 2 is indicative of an increased susceptibility to the agent. Thus, Applicants submit that the claims are clear and request that the rejections be withdrawn.

Rejections Under 35 U.S.C. § 112, Enablement

Claims 31-39

The Examiner rejects claims 31-39 under 35 U.S.C. § 112, first paragraph as not enabled, stating that the Specification is not enabling for treatment or prevention of all diseases caused by all agents.

The Specification must enable one of skill in the art, at the time of filing, to make and use the invention without undue experimentation. Enablement is determined by balancing multiple factors. These factors include: (1) the breadth of the claims, (2) the presence or absence of working examples, (3) the predictability or unpredictability of the art, (4) the amount of direction or guidance presented, (5) the nature of the invention, (6) the state of the prior art, (7) the relative skill of those in the art, and (8) the quantity of experimentation necessary. *In re Wands,* 8 USPQ 1400, 1404 (Fed. Cir. 1988).

Applicants first note that the claims are not overly broad because they recite that agents causing the disease must be non-living.

In addition, the Specification provides both guidance for and working examples of a range of disease causing agents. Example 8 on page 34 demonstrates that BMBT1-knockout mice are more sensitive to disease causing agents that expose a sulphate group than wildtype mice. The Specification presents in Example 2 (see page 28, line 25) a working example which shows that dextran sxulphate sodium (DSS) and carrageenan are ligands of DMBT1. In addition, Figure 11, which is discussed on page 27 of the Specification, presents evidence of direct interaction of Dmbt1 *in vivo* with DSS and carrageenan. Table 1, on page 30 of the Specification, also presents the results of at least twenty different agents which were tested *in vitro* and shown to bind DMBT1; many of these were tested at multiple concentrations. These agents are from bacterial cell wall components, agents with phosphate groups, and various other substances.

These combined results indicate that DMBT1 binds to the aforementioned agents and thereby protects the gut from damage caused by those agents. Consequently, the protection

against inflammatory bowel disease can be improved by administering DMBT1 to patients. Such an administration is especially advantageous in cases where the natural binding capacity of the patient for agents that expose a sulphate group or phosphate group is reduced either by mutations of DMBT1 or due to a decreased expression of DMBT1. For this reason, the use of DMBT1 for the treatment and/or prevention of diseases caused by agents that expose a sulphate group or phosphate group is enabled by the description.

Moreover, Applicants submit that the nature of DMBT1 suggests that its action is relatively predictable. The Specification states in Example 5, pages 32-33, that DMBT1 is a pattern recognition receptor (PRR), and compares it to other known PRRs like MARCO. The Specification also indicates in Examples 7 (beginning on page 33, line 35) and Example 9 (beginning on page 36, line 19) that the *in vivo* results obtained with DMBT1-/- mice, having DMBT1 localized to at least the mucous membranes, correlate with the known activities of DMBT1 in humans, and that this localization is art-recognized.

Accordingly, because Applicants do not have overly broad claims, because they have provided numerous *in vitro* examples of DMBT1 binding, and an *in vivo* model which is recognized in the art to correlate with human expression, Applicants submit that practicing the invention to the scope commensurate with the claims would not require undue experimentation. Therefore, Applicants request that the rejection be withdrawn.

Claims 61-66

The Examiner rejects claims 61-66 under 35 U.S.C. § 112, first paragraph as not enabled, stating that the Specification is not enabling "for treatment or prevention of all diseases caused by an agent possessing ≥ 1 accessible sulphate and/or ≥ 1 accessible phosphate group by administration of a therapeutically effective amount of ≥ amino acid motif comprising 11 contiguous amino acids derived from a polypeptide comprising SEQ ID NO: 1 or of a nucleic acid encoding said amino acid motif."

As a preliminary matter, Applicants point out that claims 64-66 are directed to "an in vitro method for binding an agent which possesses at least one accessible sulphate group and/or at least one accessible phosphate group."

As discussed above, Applicants have provided at least twenty examples of compounds which bind DMBT1 *in vitro* and which meet the sulphate group/phosphate group requirement. Applicants submit that based on the teachings of the Specification and the claims, which require a common structure and a common binding activity, it would not require undue experimentation for a person of skill in the art to make and use an agent which has these characteristics. Applicants respectfully request that the rejection be withdrawn.

With regard to claims 61-63, Applicants note that they have provided the sequence of the compound for administration (i.e., 11 continguous amino acids from SEQ ID NO: 1) and an *in vivo* model which is recognized in the art to correlate with human expression. Applicants submit that it would not require undue experimentation for one of skill to make and use the compound based on this known in vitro/in vivo correlation, and the known correlation between rats and humans. Accordingly, Applicants request that the rejection be withdrawn.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Susan W. Gorman Reg. No. 47,604 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: October 1, 2009

Respectfully submitted,

By _____

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Attachments: Replacement Drawings